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7900 Westpark Drive, Suite A100
McLean, VA 22102

EXAMINER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte STEFAN WILLMANN,
WALTER SCHMITT, and FRANCO FOIS

Appeal 2016-006743
Application 10/936,353¹
Technology Center 1600

Before DONALD E. ADAMS, TAWEN CHANG, and
RACHEL H. TOWNSEND, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134(a) involves claims 1–5 and 8–13 (App. Br. 1). Examiner entered a rejection under 35 U.S.C. § 101. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

STATEMENT OF THE CASE

Appellants’ disclosure “relates to a computer program for calculating the pharmacokinetic and pharmacodynamic behaviour of chemical

¹ Appellants identify the real party in interest as “Bayer Intellectual Property GmbH” (App. Br. 1).

compounds in live organisms, for example in mammals, insects or plants”

(Spec. 1: 4–6). Claim 1 is representative and reproduced below:

1. A method for determining an interaction of one or more active compounds administered to an organism with one or more compartments of the organism using a computer program consisting of individual modules with different functionalities, said computer program comprising a compound module, an organism module in a DEQ builder which automatically generates a system of coupled DEQs, and a numerical solver which solves the DEQs, said computer program further comprising a hierarchical management of parameters comprised in the individual modules with the different functionalities, wherein the modules are administered from a database of objects, said method comprising the following steps:

- A) inputting or selecting from a compound database the one or more active compounds in a model input parameter window of a graphical user interface interconnected with a compound module of a DEQ builder and one or more characteristics thereof selected from the group consisting of lipophilicity, solubility, protein binding, molecular weight, molecular volume, pKa value in the case of acids or bases, metabolic degradation rate and kinetic constants of the compound's active transporters and transmitting the one or more characteristics to the compound module;
- B) analyzing the one or more compounds with respect to the one or more characteristics in the DEQ builder;
- C) inputting or selecting an organism from a species database in a model input parameter window of a graphical user interface interconnected with an organism module of the DEQ builder comprising physiological and anatomical information which characterizes the organism and one or more anatomical and physiological compartments which form the organism;
- D) selecting one or more anatomical and physiological compartments of the organism in question in the DEQ builder as follows:

- i) in the case of mammals or insects, the selecting is from the group consisting of lungs, peripheral organs, blood vessels, arteries, veins, and blood fluid; and
 - ii) in the case of plants, the selecting is from the group consisting of xylem, phloem, root, leaf and stem;
- E) preparing a description of the one or more of the selected compartments from step C) in the DEQ builder with regard to one or more transport processes selected from the group consisting of transport from and to the one or more of the selected compartments, degradation processes, and active transport processes, and wherein the description comprises mass transport equations and kinetic reaction equations;
- F) preparing a description of the one or more transport processes mentioned in step E) and/or the degradation processes of the one or more active compounds in the organism in the DEQ builder, wherein the description comprises mass transport equations and kinetic reaction equations;
- G) automatically generating a physiologically-based model by combining the equations in steps E) and F) in a system of coupled differential equations generated automatically by the DEQ builder, the selected compartments and modules being interconnected dynamically in a hierarchical, predefined manner so that dependencies between the modules and parameters are recognized automatically, combined in the desired order and tested in the DEQ builder during the execution time of the computer program so that the individual modules are combined into an automatically generated integrated model without carrying out changes at the level of the differential equations;
- H) providing a numerical calculation of the resulting system of coupled differential equations in the numerical solver; and

- I) determining a concentration-time curve of the one or more selected active compounds from step A) in the selected compartments and outputting a graphical model in a graphical model output user interface.

(App. Br. 22–24.)

The claims stand rejected as follows:

Claims 1–5 and 8–13 stand rejected under 35 U.S.C. § 101, as directed to non-statutory subject matter.

ISSUE

Does the evidence of record support Examiner’s finding that Appellants’ claimed invention lacks subject matter eligibility?

ANALYSIS

Without additional limitations, a process that employs mathematical algorithms to manipulate existing information to generate additional information is not patent eligible. “If a claim is directed essentially to a method of calculating, using a mathematical formula, even if the solution is for a specific purpose, the claimed method is nonstatutory.” *Parker v. Flook*, 437 U.S. 584, 595[] (1978) (internal quotations omitted).

Digitech Image Techs., LLC v. Elecs. For Imaging, Inc., 758 F.3d 1344, 1351 (Fed. Cir. 2014).

As Appellants explain, “[p]hysiologically-based pharmacokinetic (PB-PK) modelling[, such as that falling within the scope of Appellants’ claimed invention,] is a mathematical modeling technique widely used in the pharmaceutical industry to predict the absorption, distribution, metabolism and excretion (ADME) of pharmaceutical substances in humans and animals” (App. Br. 8). According to Appellants, “a common defect with the known models is their rigidity” (*id.* at 9). Therefore, Appellants’ contend that their “invention solves this technical problem of systemic rigidity by a

novel modular programming method,” which “clearly improves on the existing PB-PK model technology” (*id.* at 9 and 18). Specifically, “Appellants explained how the claims’ novel and unobvious manipulation of differential equations improved an existing technology and constituted the ‘inventive concept’” (Reply Br. 1). Our reviewing court, however, has “treated analyzing information by steps people go through in their minds, or by mathematical algorithms, without more, as essentially mental processes within the abstract-idea category.” *Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1354 (Fed. Cir. 2016).

Taken as a whole, Appellants’ Brief make clear that their claimed invention employs mathematical algorithms to manipulate existing information to generate additional information (*see* Reply Br. 5 (Appellants’ “inventive concept [resides] in the claimed novel and unobvious application of the mathematical equations that improves on the existing technology”); *id.* (“Appellants’ inventive concept and contribution, is to combine the mathematical equations in the flexible, dynamic fashion required by the instant claims”)). Stated differently, Appellants’ claimed invention is to apply particular mathematical equations to a mathematical modeling technique, or, more specifically, to apply an abstract idea to an abstract idea. *Alice*, 134 S. Ct. at 2355. *Cf. Digitech*, 758 F.3d 1351 (“Without additional limitations, a process that employs mathematical algorithms to manipulate existing information to generate additional information is not patent eligible”).

On this record, Examiner finds that Appellants’ claim 1 recites the application of “a method that is computer implemented for manipulating

data without adding a patent eligible application” (Ans. 4). More specifically, Examiner finds that Appellants’

claims amount to nothing more than instructions to apply the abstract idea, *i.e.*,] gather data (determine interactions) and use a DEQ [(differential equation)] builder and solver in the confines of the computer wherein one inputs data, analyzes data, inputs more data, prepares descriptions, generates a model, provides calculations, and determines a curve for output.

(*Id.*) Thus, Appellants’ claimed invention does not “recite additional elements that amount to significantly more than the judicial exception” (*id.* at 4–5). To the contrary, Appellants concede that their claimed invention is the “application of [] mathematical equations that improves on the existing technology” of a mathematical modeling technique (Reply Br. 5). ““If a claim is directed essentially to a method of calculating, using a mathematical formula, even if the solution is for a specific purpose, the claimed method is nonstatutory.”” *Digitech*, 758 F.3d at 1351, citing *Parker*, 437 U.S. at 595 (internal quotations omitted).

CONCLUSION OF LAW

The evidence of record supports Examiner’s finding that Appellants’ claimed invention lacks subject matter eligibility. The rejection of claim 1 under 35 U.S.C. § 101, as directed to non-statutory subject matter, is affirmed. Claims 2–5 and 8–13 are not separately argued and fall with claim 1.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED